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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,928	12/21/1999	DAVID GAILLAC	017753-120	2965

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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/467,928

Applicant(s)

GAILLAC ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 16-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 16-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Detailed Office Action

37 C.F.R. § 1.114

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed 07 October, 2004, in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114.

Status of the Claims

Claims 1-12 and 16-31 are pending in the instant application. Claims 8 and 12 were amended in the response.

35 U.S.C. § 112, Second Paragraph

Claims 1-12 and 16-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The reference to a viral preparation "predominantly containing adenoviruses" is vague and indefinite since the other components of the preparation are not readily manifest. For instance, does the preparation contain other non-enveloped viruses in addition to the adenoviruses present? Does the preparation contain other non-viral ingredients? It is suggested that applicants amend the claim language to recite the following: A method of inactivating enveloped viruses in a preparation containing recombinant

adenoviruses...

Claims 1-12 and 16-31 are also vague and indefinite for omitting essential positive methods steps, such omission amounting to a gap between the steps (refer to M.P.E.P. § 2173.05(q)). *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (Bd. Pat. App. & Inter. 1986). The claims simply specify the addition of a solvent (without identifying the solvent) at a broad range of temperatures and pHs. However, the claims omit several important steps (i.e., the recovery of virus from a producer cell line; the treatment of virus with Benzonase and TWEEN 80 to remove cellular debris; inactivation of the preparation through the administration of TNBT at the proper concentration, temperature, and pH; and recovery of the virus by some type of filtration process (i.e., ion-exchange chromatography)). Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 16-31 rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed toward a method of inactivating enveloped viruses contaminating adenoviral preparations by treating said preparations with any given solvent at a wide range of pHs and temperatures. The disclosure provides an inactivation protocol involving recombinant

adenoviral preparations and specific inactivation steps involving treatment treatment with 0.3% tri-n-butyl phosphate (TNBP), 1% TWEEN 80, and benzonase. Appropriately drafted claim language directed toward this embodiment would be acceptable (i.e., A method of inactivating enveloped viruses in a preparation containing recombinant adenoviruses comprising the following steps: 1) releasing intracellular adenovirus from an infected cell line; 2) treating the released viral preparation with benzonase and TWEEN 80; 3) filtering the preparation to remove cellular debris; 4) inactivating the viral preparation through the administration of 0.6% TNBP at a pH of 8.5; 5) passing the inactivated preparation over an ion-exchange column and isolating the inactivated recombinant adenoviral preparation. The disclosure is not enabled for the full breadth of the claim language which encompasses any manner of making inactivated viral preparations.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

- 1) The disclosure fails to provide adequate guidance pertaining to suitable solvents that will result in the inactivation of

contaminating enveloped viruses but allow the recombinant adenoviruses to retain their infectivity. The term "solvent" is defined to include any substance, solution or composition capable of solubilizing lipid or of dissociating a constituent comprising one or more lipids (p. 7, l. 25-29). Thus, this claim language encompasses a large number of sundry compounds with different physical and chemical characteristics. With the exception of TNBP, which was added in well-defined amounts, no guidance was provided concerning other acceptable solvents. Thus, the skilled artisan has been asked to guess as to which other solvents might be useful.

2) The disclosure fails to provide adequate guidance pertaining to suitable temperature and pH ranges that will achieve the desired result. The claims encompass temperature ranges between -5°C and 50°C and pH ranges between 5 and 9. These ranges encompass considerable temperature and pH differences. The precise conditions required for inactivation while retaining recombinant adenoviral activity is not clear. It seems likely though, that the various conditions claimed will result in inactivation. For instance, at -5°C the skilled artisan might not expect all the contaminating viruses to be inactivated.

3) The disclosure fails to provide a sufficient number of method steps to perform and complete the claimed methodology. As noted *supra* in the 35 U.S.C. § 112, second paragraph, rejection, the claims omit a number of salient steps that are required for completion.

4) The claims are of considerable breadth and encompass any given solvent under a wide range of pHs and temperatures. However, the disclosure fails to provide sufficient support for the breadth of the claim language.

5) The disclosure fails to provide a reasonable number of working embodiments. All of the examples employed TNBP (0.3% final concentration), 2% TWEEN 80, pH 8.5, and a temperature of 4°C. The

disclosure fails to describe the utilization of any other solvents, detergents, or reaction conditions. Accordingly, when all the aforementioned factors are considered *in toto*, the skilled artisan would reasonably conclude that undue experimentation would be required to practice the claimed invention.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

26 December, 2004